



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 16

[Docket No. FDA-2013-N-0365]

Administrative Detention of Drugs Intended for Human or Animal Use; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule entitled "Administrative Detention of Drugs Intended for Human or Animal Use" that appeared in the Federal Register of May 29, 2014 (79 FR 30716). The rule sets forth the procedures for detention of drugs believed to be adulterated or misbranded and amends the scope of FDA's part 16 regulatory hearing procedures to include the administrative detention of drugs. The rule published with incorrect statements regarding the impact of the final rule on small entities. This document corrects those errors.

DATES: Effective [insert date of publication in the Federal Register] and applicable beginning June 30, 2014.

FOR FURTHER INFORMATION CONTACT: Emily Leongini, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4339, Silver Spring, MD 20993-0002, 301-796-5300, FDASIAImplementationORA@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of May 29, 2014, in FR Doc. 2014-12458, the following corrections are made:

1. On page 30718, in the third column, under "Analysis of Impacts (Summary of the Regulatory Impact Analysis)," the last sentence of the second paragraph is corrected to read: "FDA certifies that this final rule will not have a significant economic impact on a substantial number of small entities."

2. On page 30719, in the first column, the third sentence of the last full paragraph is corrected to read: "We certify that this final rule will not have a significant economic impact on a substantial number of small entities."

Dated: April 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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